

AGENDA

GASTROENTEROLOGY AND UROLOGY DEVICES PANEL of the MEDICAL DEVICES ADVISORY COMMITTEE

Food and Drug Administration – White Oak Campus
Building 31 – The Great Room, B & C
Silver Spring, MD

May 14, 2015

Panel Chairperson
Mark A. Talamini, M.D.

Designated Federal Officer
Natasha G. Facey

- 8:00 a.m. Call to Order
 Panel Introduction
 Conflict of Interest Statement
- 8:15 a.m. **Center for Devices and Radiological Health**
 Part I: FDA Opening Remarks
 Stephen Ostroff, M.D., FDA Commissioner (Acting)
- Part II: Timeline of Events
 Suzanne Schwartz, M.D., M.B.A
- Part III: Introduction to Endoscopic Retrograde Cholangiopancreatography (ERCP)
 Herb Lerner, M.D.
- Part IV: Overview of Duodenoscopes and Reprocessing Procedures
 Shani Haugen, Ph.D.
- Part V: Automated Endoscope Reprocessors (AERs) and Sterilization
 Elaine Mayhall, Ph.D.
- Part V: Medical Device Adverse Event Reports
 Jose Delgado Donayre, M.D.
- 9:30 a.m. Clarifying Questions from the Panel
- 9:45 a.m. Break
- 10:00 a.m. Manufacturer Presentations

AGENDA, continued

May 14, 2015

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| 11:00 a.m. | Clarifying Questions from the Panel |
| 11:15 a.m. | Infections: Hospitals' Perspective |
| 11:45 a.m. | Clarifying Questions from the Panel |
| 12:00 p.m. | Lunch |
| 1:00 p.m. | Open Public Hearing* |
| 2:00 p.m. | Clarifying Questions from the Panel |
| 2:15 p.m. | Infections: Hospitals' Perspective (continued) |
| 3:15 p.m. | Clarifying Questions from the Panel |
| 3:30 p.m. | Break |
| 3:45 p.m. | CDC Outbreak Investigation
Alexander J. Kallen, M.D., M.P.H. |
| 4:15 p.m. | Clarifying Questions from the Panel |
| 4:30 p.m. | FDA Outbreak Investigation
Suzanne Schwartz, M.D., M.B.A. |
| 4:45 p.m. | Clarifying Questions from the Panel |
| 5:00 p.m. | Reprocessing Verification Testing
Michelle Alfa, Ph.D. |
| 5:30 p.m. | Clarifying Questions from the Panel |
| 5:45 p.m. | Session Adjournment |

***Open Public Hearing:** Interested persons may present data, information or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the Panel will speak at this time. After they have spoken, the Chair may ask them to remain if the Panel wishes to question them. The Chair may recognize unscheduled speakers if time allows. Only the Panel may question speakers during the Open Public Hearing. Public attendees may not participate except at the specific request of the Panel Chair.

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GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
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MEDICAL DEVICES ADVISORY COMMITTEE

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May 15, 2015

Panel Chairperson
Mark A. Talamini, M.D.

Designated Federal Officer
Natasha G. Facey

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| 8:00 a.m. | Call to Order
Panel Introduction
Conflict of Interest Statement |
| 8:15 a.m. | FDA: Recap of Day 1 |
| 8:30 a.m. | CDC Surveillance Protocols
Matthew Arduino, M.S., Dr.PH. |
| 9:00 a.m. | Clarifying Questions from the Panel |
| 9:15 a.m. | Open Public Hearing* |
| 10:15 a.m. | Clarifying Questions from the Panel |
| 10:30 a.m. | Break |
| 10:45 a.m. | ERCP Scopes: A Need to Shift from Disinfection to Sterilization?
William Rutala, Ph.D., M.P.H. |
| 11:15 a.m. | Clarifying Questions from the Panel |
| 11:30 a.m. | Ethylene oxide sterilization – EPA perspective
Timothy Leighton |

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AGENDA, continued

May 15, 2015

12:00 p.m.	Clarifying Questions from the Panel
12:15 p.m.	Lunch
1:15 p.m.	Panel Deliberations
2:00 p.m.	FDA Questions to the Panel
3:00 p.m.	Break
3:15 p.m.	FDA Questions to the Panel (continued)
4:30 p.m.	FDA Summations
5:00 p.m.	Meeting Adjournment